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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,507	02/18/2004	Rafail Zubok	532/3X8	2937

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EXAMINER

CUMBERLEDGE, JERRY L

ART UNIT	PAPER NUMBER
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3733

MAIL DATE	DELIVERY MODE
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09/07/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/781,507

Applicant(s)

ZUBOK ET AL.

Examiner

Jerry Cumberledge

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 7-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 7-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 May 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5 and 7 are rejected under 35 U.S.C. 102(e) as being anticipated by Foley (US Pat. 6,991,654).

Foley discloses a method of replacing at least a portion of an intervertebral disc of an intervertebral disc space of a spinal column, the intervertebral disc space defined at least by respective endplates of first and second adjacent vertebral bones, the method comprising: inserting at least one intervertebral disc replacement trial into the intervertebral disc space to distract same in a direction along a longitudinal axis of the spinal column (column 4, lines 24-34); and simultaneously inserting first and second members (Fig. 9, refs. 113 and 115) of an intervertebral disc replacement device into an intervertebral disc space of the spinal column (column 8, lines 16-19), wherein first and second articulation surfaces (Fig. 9, ref. 122a and ref. 122b) of the respective first and second members of the intervertebral disc replacement device are in substantial

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registration with one another during their simultaneous insertion into the intervertebral disc space (column 8, lines 17-20). The step of inserting at least one intervertebral disc replacement trial includes using a set of intervertebral disc replacement trials to displace the intervertebral disc space, at least two of the intervertebral disc replacement trials having differing head thicknesses to facilitate distraction of the vertebral bones along the longitudinal axis (column 1, lines 21-26). The method of further comprises inserting a first of the trials into the intervertebral disc space to facilitate at least some distraction of the first and second vertebral bones; and inserting a second of the trials into the intervertebral disc space to facilitate at least some further distraction of the first and second vertebral bones, where the second trial has a larger head thickness than that of the first trial (column 1, lines 21-26). The method further comprises repeating the insertion of further trials having larger and larger head thicknesses to facilitate the distraction of the vertebral bones to a target distance (column 1, lines 21-26), wherein the target distance is one that substantially maximizes the intervertebral space while substantially preserving an annulus and ligaments associated with the vertebral bones (column 16, lines 39-43). The method further comprises leveraging a handle of the at least one trial to facilitate the distraction of the first and second vertebral bones (column 8, lines 11-15). The method further comprises orienting and maintaining first and second articulation surfaces of the respective first and second members of the intervertebral disc replacement device in substantial registration with one another during their simultaneous insertion into the intervertebral disc space (column 8, lines 17-20). The method further comprises manipulating the first and second members as a single unit

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by way of an intervening insertion plate (Fig. 7, ref. 108)(column 8, lines 4-16) such that they may be at least one of inserted into and moved within the intervertebral disc space without substantially changing their orientation with respect to one another (column 8, lines 17-20). The method further comprises using an insertion handle (Fig. 7, ref. 98) that is adapted to detachably engage the insertion plate in order to manipulate the first and second members as a single unit (column 8, lines 17-20).

Claim 10 is rejected under 35 U.S.C. 102(b) as being anticipated by Robioneck et al. (US Pat. 6,296,647 B1).

Robioneck et al. disclose a method of replacing at least a portion of an intervertebral disc of an intervertebral disc space of a spinal column, the intervertebral disc space defined at least by respective endplates of first and second adjacent vertebral bones, the method comprising: maintaining first and second members (Fig. 2, refs. 10 and 12) of an intervertebral disc replacement device as a single assembly by way of an insertion plate (Fig. 2, comprising refs. 32, 20, 22 and 56) (column 6, lines 42-45 and column 3, lines 50-60), wherein first and second articulation surfaces (Fig. 2, surfaces between refs. 10 and 12) of the respective first and second members of the intervertebral disc replacement device are in substantial registration (Fig. 2) with one another during their simultaneous insertion into the intervertebral disc space (column 6, lines 61-64); using an insertion handle (Fig. 15, ref. 116) that is adapted to detachably engage the insertion plate in order to manipulate the first and second members as a single unit such that they may be at least one of inserted into and moved within the

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intervertebral disc space without substantially changing their orientation with respect to one another (column 6, lines 61-64); and manipulating an actuator of the insertion handle to cause detachment of the insertion plate from the insertion handle (column 6, lines 2-3). Robioneck et al. further disclose engaging the insertion handle with the insertion plate (column 6, lines 61-64); using the insertion handle to urge the first and second members of the intervertebral disc replacement device into a target position within the intervertebral disc space (column 6, lines 61-64); and driving at least one screw through at least one hole of the first member of the intervertebral disc replacement device and into the at least one hole to connect the first member to the first vertebral bone (column 3, lines 66-67 and column 4, lines 1-3); and disengaging the insertion handle from the insertion plate (column 7, lines 14-17). Robioneck et al. further disclose engaging the insertion handle with the insertion plate (column 6, lines 61-64); using the insertion handle to urge the first and second members of the intervertebral disc replacement device into the target position within the intervertebral disc space (column 6, lines 61-64); and driving at least one screw through at least one hole of the second member of the intervertebral disc replacement device and into the at least one hole to connect the second member to the second vertebral bone (column 3, lines 66-67 and column 4, lines 1-3); and disengaging the insertion handle from the insertion plate (column 7, lines 14-17). The method further comprises removing the insertion plate (column 7, lines 14-17).

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Foley (US Pat. 6,991,654).

With regard to claim 8, Foley discloses the claimed invention except for the method including a device with an insertion handle being detachable from the insertion plate. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have constructed the insertion handle of Foley being detachable from the insertion plate of Foley, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlichman*, 168 USPQ 177, 179.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Foley (US Pat. 6,991,654) in view of Banick et al. (US Pub. 2003/0093153 A1).

Foley discloses the claimed invention except for the insertion handle, insertion plate and the first and second members being provided in a sterile assembly in a package for access by a surgeon.

Banick et al. disclose packing various surgical devices in sterile packages (paragraph 0037), in order to ensure that, during a given surgical procedure, a surgeon uses devices that have similar mechanical and biological properties (paragraph 0038).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have modified the method of Foley to include the step of providing surgical devices in a sterile package for access by the surgeon of Banick et al., in order to ensure that a surgeon uses devices that have similar mechanical and biological properties during a given surgical procedure (paragraph 0038).

Claims 11-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robioneck et al. (US Pat. 6,296,647 B1) in view of Bray (US Pat. 6,235,034 B1).

Robioneck et al. disclose the claimed invention except for the method further comprising steps of using a drill guide, a drill and drilling into vertebral bone and disengaging the drill guide from the insertion plate.

Bray discloses using a drill guide, a drill and drilling into bone and disengaging the drill guide from the insertion plate (column 3, lines 26-39), in order to ensure that the screw hole is drilled at a proper angle, in order to prevent unwanted widening of a screw hole once the screw is placed in the hole (column 3, lines 39-42).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have modified the method of Robioneck et al. to include the use of a drill guide and a drill, and drilling into bone and disengaging the drill guide from the insertion plate of Bray, in order to ensure that the screw hole is drilled at a proper

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angle, in order to prevent unwanted widening of a screw hole once the screw is placed in the hole (column 3, lines 39-42).

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Robioneck et al. (US Pat. 6,296,647 B1) in view of Bray (US Pat. 6,235,034 B1) further in view of Lyons et al (US Pat. 6,413,259 B1).

Robioneck et al. in view of Bray disclose the claimed invention except for the method further comprising fastening at least one screw retaining element to at least one of the first member of the intervertebral disc replacement device, the second member of the intervertebral disc replacement device, the first vertebral bone, and the second vertebral bone, wherein the screw retaining element is operable to resist the at least one screw of the first member and the at least one screw of the second member from backing out of the respective vertebral bones.

Lyons et al. disclose screw retaining elements (Fig. 1 ref. 22) that cover different portions of a device (Fig. 1) in order to prevent backing out of screws (column 4, lines 47-49) (column 62-64).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have modified the method of Robioneck et al. in view of Bray to include the step of fastening at least one screw retaining element to a device of Lyons et al., in order to prevent backing out of screws (column 4, lines 47-49) (column 62-64).

Response to Arguments

Applicant's arguments filed 06/18/2007 have been fully considered but they are not persuasive.

With regard to Applicant's argument that none of the prior art references utilized by the examiner teach or suggest performing those method steps in connection with a two-piece articulated implant device, the examiner notes that the claims require "...first and second articulation surfaces..." not an articulated implant device. Both the Foley reference and the Robioneck reference disclose at least two surfaces that can be named "articulation" surfaces. The surfaces can reasonably be called articulation surfaces since the surfaces are distinct from each other and can articulate with respect to each other before they are inserted into the body.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Cumberledge whose telephone number is (571) 272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JLC



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